FINAL/APPROVED (03/29/2007)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR REGULATORY REVIEW

March 7, 2007
Fifth Floor
Conference Room 1

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A working meeting of an ad hoc committee of the Board of Pharmacy for the purpose of conducting a review of regulations was called to order at 9AM.

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT: Willie Brown
Michael Stredler
David Kozera
Jennifer Edwards

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Caroline Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst

REVIEW: The committee completed the reviews of Parts VI, VII, VIII, IX, XVI that had not been previously reviewed. It also looked at the recommendations from the previous meeting and made some additional recommendations to some sections. Notes on all recommendations are included in these minutes as Attachment 1

ADJOURN: The meeting was adjourned at approximately 2PM.

Elizabeth Scott Russell
Executive Director

John O. Beckner, Chairman

Date

Part I. General Provisions

18VAC110-20-10. Definitions.

- **long term care facility to include other facilities? (NABP rules for institutional pharmacy)**
- **Definition of CE/CEU- ACPE may be redefining its definition.**
- **No definition of chart order-needs to be loose enough to include electronic chart orders.**
- **may want to define what we mean by the term "initial" used in a number of places throughout the regulation, e.g. can this be a stamped set of initials**

18 VAC 110-20-15. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

18VAC110-20-20. Fees.

Part II. Licensure Requirements for Pharmacists

18VAC110-20-30. Requirements for practical experience.

- **may just want to identify as possibly inconsistent with new ACPE standards for experiential training, and that NABP is amending model rules. The Board may want to consider amending practical experience requirements to conform to these in order to facilitate reciprocity.**
- **ACPE standards for preceptors and practical experience may be changing.**
- **Unclear when first professional year ends.**
- **ACPE may start allowing practical experience within the first year.**

18VAC110-20-40. Procedure for gaining practical experience.

- **pharmacists in military hospitals outside the US as preceptors (Tou Yang, Seoul, South Korea**
- **Does not allow for accepting practical experience outside US.**
- **Does not allow for pharmacists in military hospital outside the US to serve as preceptors.**
- **Number of interns that may be supervised may be problematic when schools' programs overlap.**

18VAC110-20-50. Curriculum and approved schools of pharmacy.

- **(A, 1) is now outdated.**

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.

- **Does not require applicant to wait a certain time period to take law exam if failed multiple times. Concern is with security of test items for computerized testing.**
- **Add guidance document 110-39 related to ADA accommodations**

18VAC110-20-70. Requirements for foreign-trained applicants.

- **clarify that must pass the FPGEE before becoming an intern (staff, and clarification of statute requirements)**
- **Does not require expiration date on intern licenses.**
- **No mechanism for extending when good cause shown.**

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.

18VAC110-20-80. Renewal and reinstatement of license.

- **(I)- No provision to notify the Board electronically.**
- **Requirement of annual renewal cycle may be costly or unnecessary.**
- **#I also needs a time frame instead of "immediately". 14 days was discussed.**

18VAC110-20-90. Requirements for continuing education.

- **ACPE going to a topic designator system.**
- **(A)- Date listed is unnecessary.**
- **(D)- May need to maintain CE for 3 years if Board is going to audit for previous two renewal cycles.**

18VAC110-20-100. Approval of continuing education programs.

- **Board approved programs do not have expiration dates.**
- **No mechanism for renewing programs.**
- **(6)- May need to maintain records for 4 years for auditing purposes.**

Part III. Requirements for Pharmacy Technician Registration

18VAC110-20-101. Application for registration as a pharmacy technician.

- **Does not include language of 18VAC110-20-111 (C) which allows individual to work for no more than 9 months.**

18VAC110-20-102. Criteria for approval for training programs.

- **No expiration date assigned to Board approved programs.**
- **No mechanism for renewing or reviewing programs for law updates, etc.**
- **No mechanism for submitting changes to programs.**
- **(C)- does not allow for restricted licensees to serve as instructors.**
- **Does not require criminal background check.**

18VAC110-20-103. Examination.

- **Add guidance document 110-39 related to ADA accommodations**

18VAC110-20-104. Address of record.

- **Thirty day requirement may be too long.**
- **Does not allow for electronic communication.**

18VAC110-20-105. Renewal and reinstatement of registration.

- **reactivating vs. reinstatement-statute says 15 hours for each year for reactivating while we have a 60 hour cap on reinstatement. need to change statute or reg.**

18VAC110-20-106. Requirements for continued competency.

- **(B)- Does not appropriately reference 18VAC110-20-100 in this section, only 18VAC110-20-90.**
- **D needs to be changed from 2yr to 3 yr to accommodate our audits**

Part IV. Pharmacies

18VAC110-20-110. Pharmacy permits generally.

- **Consider adding language about how far from the opening date may a permit be issued.**
- **not be allowed to operate from a private residence or dwelling**
- **consider specifying long-standing policy that more than one permit may not be issued to operate out of the same Rx department space to include other types of permits for licenses, e.g. a pharmacy could not also get a second pharmacy permit, or a manufacturer's permit to operate both businesses out of the same physical space.=**
- **suggestion that instead of immediately returning permit to the board, may want to require that the PIC mark it VOID and the effective date of termination as PIC**
- **consider not mandating that an outgoing PIC be required to take inventory, but that if they want to the owner has to allow it if the outgoing PIC wants to do one unless there is good cause shown as to why they will not allow it.**
- **clarify that pharmacy should not share same physical space with another licensed facility**
- **Add guidance document 110-33 related to pharmacy interns working as pharmacy technicians, here or to 18VAC110-20-111**

18VAC110-20-111. Pharmacy technicians.

- **requirement for pharmacy to maintain start date & completion date for tech in training**
- **requirement for techs to post registrations**
- **(C)- This section is located oddly since A and B reference site specific tech training programs and C references Board approved training programs.**
- **clarification needed as to whether a PTCB certified pharmacy tech can be unregistered and working as a trainee while enrolled in an approved training program, even though they don't need it.**

18VAC110-20-120. Special or limited-use pharmacy permits.

- **add free clinic guidance doc 110-22**
- **look at allowing a community pharmacy serving free clinic to get a second permit**

18VAC110-20-121. Innovative program approval.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.

- **Require closing pharmacy to transfer prescription files somewhere where a patient can access.**

18VAC110-20-135. Change of hours in an existing pharmacy.

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

18VAC110-20-150. Physical standards for all pharmacies.

- **(B)- does not include actual effective date of chapter.**

18VAC110-20-160. Sanitary conditions.

18VAC110-20-170. Required minimum equipment or resources.

18VAC110-20-180. Security system.

- **put effective dates in #5 & 6 (11/4/1993)**
- **Does not require alarm to be “hard-wired” (this may be problematic based on new wireless technology which utilizes a monitored battery)**
- **May be problematic to exempt some pharmacies from having an alarm system.**
- **Require alarm to be monitored.**

- **#7 want to change to say prior to closing for business instead of within 72 hours**

18VAC110-20-190. Prescription department enclosures; access to prescription department.

- **(B, 2)- does not require the "other secured place" to be within the pharmacy.**
- **Clarify #3 & #4 to allow for drop down gates, therefore door with lock would be unnecessary-however, may still want to require a lock for times when pharmacist may not want to pull down gates.**

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

- **rules for automated will call devices (current pilot)**
- **storage of will-call, confusion as to whether they have to be in Rx Dept alarmed after hours, reach over a counter and access them (staff)**
- **may want to clarify the question about medical devices being able to be outside the Rx dept.-similar to paraphernalia.**

18VAC110-20-210. Disposal of drugs by pharmacies.

- **Identified as being problematic.**

Part V. Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

18VAC110-20-230. Qualification as a nuclear pharmacist.

Part VI. Drug Inventory And Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

- **require a perpetual inventory for CII and possibly hydrocodone products, to include a monthly count-back to reconcile count- to be performed at least every 30 days**
- **Strike #4 (confusing and is only for Board's benefit)**
- **Clarify storage of records- #3 location may be building where drugs are located.**
- **Add requirement to maintain CVI invoices.**
- **Add guidance document 110-35 to include allowance for retail pharmacies to use chart orders**

18VAC110-20-250. Automated data processing records of prescriptions.

18VAC110-20-255. Other dispensing records.

18VAC110-20-260. [Repealed]

Part VII. Prescription Order And Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

- **how paragraph C applies in institutions- primarily about initialing the labels on IV's and maybe first doses, with no permanent record**
- **Look at ratios (consider open-ended; possibly needs other safety parameters around it)**
- **270 E- Add statement to retain knowingly forged prescription (possibly after verifying with prescriber)**

18VAC110-20-275. Delivery of dispensed prescriptions.

- **require that manual/contract be maintained at both pharmacy and ADS**
- **Strike "if required by law" in B2h & C2E (obtaining consent, etc)**
- **Add allowance for tech to serve as responsible party at an alternate delivery site (follow pilot program- see if reg change is needed)**
- **Possibly beef-up who may have alternate delivery site, as approved by Board (patient compliance/safety versus convenience)**

18VAC110-20-276. Central or remote processing.

18VAC110-20-280. Transmission of a prescription order by facsimile machine.

- **clarify that hospice can be home hospice**
- **need to change "nursing home" to LTCF**
- **clarify if nurse may fax verbal order as prescriber's agent even though not being faxed from prescriber's practice location;(In #4, add or except done by authorized agent in #3)**
- **Refers 54.1-3408.01 "C"; should be "B".**
- **Add allowance to fax CIII-VI written prescriptions to pharmacy from a facility such as LTC & establish time requirements to follow-up with hard copy**

18VAC110-20-285. Electronic transmission of prescriptions from prescriber to pharmacy.

- **change definition of agent to 3408.03C not D**

18VAC110-20-290. Dispensing of Schedule II drugs.

18VAC110-20-300. [Repealed]

18VAC110-20-310. Partial dispensing of Schedule II prescriptions.

18VAC110-20-320. Refilling of Schedule III through VI prescriptions.

- **D- Allow for early refill due to good cause or absence (vacation)**
- **reword last part of D to clarify that intent is about timing of refill and not about the ability to change Rx based on the strength of drug in stock.**

18VAC110-20-321. Compounding.

Part VIII. Labeling and Packaging Standards for Prescriptions

18VAC110-20-330. Labeling of prescription as to content and quantity.

- **Add here or possibly create 335- ability to provide alternative labeling/counseling/med guides (possibly include disclaimer to verify with someone else; may need to require both English & other; check with other states)**

18VAC110-20-340. Packaging standards for dispensed prescriptions.

- **Add guidance document 110-12 to B.**
- **Add guidance document 110-23.**

18VAC110-20-350. Special packaging.

- **Repeal entire regulation and rely on statute.**

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

- **Add pharmacist's initials to filling record for automated counting devices or dispensers (to C, f to verify process as stated in A)**

- **Add guidance document 110-16.**
- **Clean up #4 & change "second" to "subsequent" lots.**

Part IX. Standards for Prescription Transactions

18VAC110-20-360. Issuing a copy of a prescription that can be refilled.
- **See if #2 is same as DEA. If not, consider striking #2 & #3.**

18VAC110-20-370. (Repealed)

18VAC110-20-380. (Repealed)

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.
- **Add guidance document 110-20**

18VAC110-20-395. Purchase of drugs.
- **Clarify to allow for non-licensed warehouse to sell to pharmacy (intra-company sales)**

18VAC110-20-400. Returning of drugs and devices.
- **Add hospital as referenced in 3411.1**

18VAC110-0-410. Permitted physician licensed by the board.
- **Add "pharmacy" term to paragraph A.**

18VAC110-20-411 through 18VAC110-20-416. (Repealed).

18VAC110-20-417 to 18VAC110-20-419. [Reserved]

Part X. Unit Dose Dispensing Systems

18VAC110-20-420. Unit dose dispensing system.

18VAC110-20-425. Robotic pharmacy systems.
- **Does not include 5% pharmacist check allowance as stated in many robot applications.**

Part XI. Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.
- **quantity or duration of order?**
- **request to add suture kits and anesthesia kits to list of thing that can be stored outside the pharmacy**
- **(D)- Is unclear if non-pharmacy personnel may be unlicensed personnel.**
- **Consider requirement of monthly drug review similar to LTC if patient stays longer than 30 days (ex.-acute psych hospitals)**

18VAC110-20-450. After-hours access to the pharmacy.
- **after-hours access to pharmacy-now in conflict with JCHAO standards, so may want to list as a problem in NOIRA and look to repeal that section. Maybe come up with alternative language for a night cabinet.**

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.
- **pharmacist required to check before leaving the pharmacy (staff)**

- **manual delivery record may want to allow off-site as well as requiring that it be kept and for 2 years**
- **may want to want to allow the audit records to be kept somewhere off-site-not in the pharmacy**
- **Does not require records for Schedule VI, only II-V.**

18VAC110-20-470. Emergency room.

18VAC110-20-480. (Repealed)

18VAC110-20-490. Automated devices for dispensing and administration of drugs.

- **for 490 (1) track the language in 555 (5) related to requiring a pharmacist to check delivery orders before they leave the pharmacy (staff)**
- **maintaining record of filling for CVI not addressed**
- **Does not allow pharmacies to keep records off-site.**
- **Confusion with 5C as to what a sampling means (all drugs dispensed from each device within 24 hours or all dispensed to a particular pt within 24 hours or all of a drug dispensed within 24 hours)**

18VAC110-20-500. Licensed emergency medical services agencies program.

- **pharmacist required to check before sealing (staff)**
- **some ability to do 1:1 exchange without having to have the CSR (various, staff)**
- **ability to have fluids outside the box (various, staff)**
- **Does not include similar language regarding methods of sealing box as found in 18VAC110-20-540 and 18VAC110-20-550.**
- **OEMS had issue with signing by medical pracitioner or the OMD- resolved??**

18VAC110-20-510. Identification for medical intern or resident prescription form in hospitals.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

18VAC110-20-520. Drugs in long-term care facilities.

- **needs to be moved into Part XII (staff)**
- **allow stocking of OTC meds (Beverley Group); should prescription be necessary for OTC's**

Part XII. Pharmacy Services to Long-Term Care Facilities

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

- **limit the number of reviews that may be done by one pharmacist in a day-recommendation not to exceed 75 patient reviews per day (Empsy Munden)**
- **Does not address possible allowance for dispensing set quantity of drug from discharge orders that do not specify quantity or duration of order.**
- **Need to reference 210**

18VAC110-20-540. Emergency drug kit.

18VAC110-20-550. Stat-drug box.

- **change language to allow nurse in assisted living to access even if use med aides - Guidance Doc 110-11(numerous requests including Neighborcare, Virginia Association of Nonprofit Homes for the Aging (VANHA), and Virginia Health Care Association);**

- **introductory paragraph-the "shall" should be a "may" and I would even say "may only" and change the wording to say nurses rather than persons licensed to administer**
- **Allowed quantity of doses may be too low.**
- **Number of drugs per therapeutic class may be too restrictive.**
- **Does not allow for oral Schedule II drugs which may be problematic.**

18VAC110-20-555. Use of automated dispensing devices.

- **maintain record of filling CVI?**
- **in #5 need to require that that record be maintained and for how long, or do a catch all at the end that says something like all records required by this section shall be maintained for 2** years.
- **may want to want to allow the audit/delivery records to be kept somewhere off-site-not in the pharmacy**
- **Does not require records or audits of Schedule VI, only II-V.**
- **Perhaps look at allowing override capability for emergency meds (at least within hospital with a LTC setting)**

18VAC110-20-560. Floor stock.

Part XIII. Other Institutions and Facilities

18VAC110-20-570. Drugs in infirmaries/first aid rooms.

- **Strike D**
- **C,1- Change "chapter" to "section" and add "when written prescription may not be readily obtained"**
- **Strike "#1" & "#2", but keep statements.**
- **Change "controlled drug" to "controlled substance"**

18VAC110-20-580. Humane societies and animal shelters.

- **A,1- add that such record of certification be maintained at facility**
- **Confusion with "animal shelter"**
- **Clarify that drugs must be administered at permitted facility (either make new one or put in #3)**

18VAC110-20-590. Drugs in correctional institutions.

- **allow the use of samples in correctional centers (Colton Hand-pilot) and drugs from places other than pharmacies**
- **take the definition part out and add it to 10**
- **Missing letter A.**
- **Does not define correctional facility.**
- **Does not allow for the use of other types of forms to accompany returned drugs to the pharmacy- is restricted to drug administration record.**
- **Allowed number of drugs per therapeutic class and number of doses in stat box and emergency box is too few, especially for alcohol withdrawal in correctional facilities.**
- **Confusion as to whether correctional health assistants may access stat and emergency boxes or must it be a licensed individual.**
- **No provision for jails to stock tetanus or vaccines without a controlled substances registration.**

Part XIV. Exempted Stimulant or Depressant Drugs and Chemical Preparations

18VAC110-20-600. Excluded substances.

18VAC110-20-610. Exempted chemical preparations.

18VAC110-20-620. Exempted prescription products.

18VAC110-20-621. Exempted anabolic steroid products.

18VAC110-20-622. Excluded veterinary anabolic steroid implant products.

- **Federal regulations will be checked to ensure that these regulations are still consistent**

Part XV. Medical Equipment Suppliers

18VAC110-20-630. Issuance of a permit as a medical equipment supplier.
18VAC110-20-640 through 18VAC110-20-670. (Repealed.)
18VAC110-20-680. Medical equipment suppliers.

Part XVI. Controlled Substances Registration for Other Persons or Entities

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

- **add the requirement for inspection prior to issuance, and require that on any change of location of drug stock or remodeling have to make application and be inspected.**
- **include 14 day requirement and drugs may not be stocked until approved-track language in 140C**

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

- **change in responsible party-have to send in old registration?**
- **Look at current technology re: alarm standards- battery operated alarms (180 & 700)**
- **C- clarify that prescribers, nurses, pharmacists & techs may access controlled substances?? (who may access drugs); clarify that this is defining who may be the responsible party; strike for emergency situation.**
- **#3 clarify that this is defining who may be the supervising practitioner- PA's, NP's not captured.**

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

- **Alarm requirements- battery technology.**

18VAC110-20-720. Requirements for recordkeeping.

18VAC110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.